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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------|
| 09/631,339   | 08/03/2000  | Carl T Wittwer       | 7475-66667                     | 9681             |
| 49437  | 7590        | 08/24/2005           |                                |                  |
| ROCHE<br>11 SOUTH MERIDAN STREET<br>INDIANAPOLIS, IN 46204 |             |                      | EXAMINER<br>BEISNER, WILLIAM H |                  |
|  |             |                      | ART UNIT                       | PAPER NUMBER     |
|  |             |                      | 1744                           |                  |
| DATE MAILED: 08/24/2005                                    |             |                      |                                |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/631,339

**Applicant(s)**

WITTWER ET AL.

**Examiner**

William H. Beisner

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005 and 13 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-12 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12 and 15-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 includes an embodiment that includes a capillary tube with an inner diameter in the range from about 0.02mm to about 0.1 mm in combination with a wall thickness of 0.1mm. While the originally filed disclosure provides support for a capillary tube having a wall thickness of 0.1mm, this is only when the tube has an inner diameter of 0.8mm and an outer diameter of 1mm (See page 54, lines 5-8, of the instant specification). While the originally filed disclosure provides support for a capillary tube having an inner diameter between about 0.02mm and about 0.1mm (See page 19, lines 17-18), the originally filed disclosure fails to support a tube with this claimed diameter and a wall thickness of about 0.1 mm. Applicants' comments do not point to any disclosure in the 79 page specification that provides support for this newly recited claim limitation. One of ordinary skill in the art could not have clearly envisioned that this claim limitation was considered to be part of the claimed invention as the time of the filing of the instant specification.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 7, 8, 9, 15, 16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by von Behrens (US 3,914,985).

With respect to claims 7 and 21, the reference of von Behrens discloses a container (12) for holding a fluidic biological sample that includes a receiving portion (12a) and a reaction portion (12b). A liquid sample positioned within the receiving portion (12a) is capable of flowing into reaction portion (12b). As shown in Figure 1, the receiving portion (12a) has a volume greater than the reaction portion (12b). The reaction volume is not greater than 100 $\mu$ l (See column 4, lines 26-35). With respect to the recited thermal conductivity of the reaction portion, the reference of von Behrens discloses that the reaction portion (12b) is made of glass (See column 4, line 33) which is a material disclosed by the instant specification as a material with the claimed thermal conductivity (See page 53 of the instant specification). The reference of von Behrens discloses that the end of the reaction portion (12b) can be permanently sealed (See column 5, lines 57-67, and Figure 6). With respect to the claimed “wherein the closed end is formed for optical transmissibility through the closed end”, the closed end of the reference of

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von Behrens as discussed previously is considered to meet this claim limitation since it is made of a transparent glass (See column 5, lines 57-67, Figure 6 and column 4, line 33).

With respect to claims 8 and 9, the reaction volume is not greater than 1ml and is between about 0.01microliter to about 100micrliter (See column 4, lines 29-32).

With respect to claims 7 and 15, the reaction portion has a v:sa ratio of less than 1mm or 0.25mm (See column 4, lines 26-35).

With respect to claim 16, the glass capillary is inherently optically transmissible for light of the claimed wavelength.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985).

The reference of von Behrens has been discussed above.

With respect to claim 11, the specifics of the interface between the funnel-shaped upper portion (12a) and the lower portion (12b) would have been well within the purview of one having ordinary skill in the art while maintaining a fluid seal between the separate elements (See column 5, lines 33-47).

9. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Gerarde (US 3,518,804).

The reference of von Behrens has been discussed above.

Claims 17 and 18 differ by reciting that the device includes a plug for the receiving portion (12a) of the device.

The reference of Gerarde discloses that it is known in the art to seal the reservoir end of a micropipette device (10) with a plug (24).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to seal the open end of the upper portion (12a) of the device of von Behrens with a plug device as suggested by the reference of Gerarde for the known and expected result of providing an art recognized means for sealing the contents of the pipette device with respect to the atmosphere for protection and/or stabilization.

10. Claims 1-6 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerarde (US 3,518,804) in view of Gerarde (US 3,045,494).

The reference of Gerarde discloses a container (10) for holding a fluidic biological sample that includes a receiving portion (12) and a reaction portion (14). A liquid sample positioned within the receiving portion (12) is capable of flowing into reaction portion (14). As shown in Figure 1, the receiving portion (12) has a volume greater than the reaction portion (14). The reaction volume is not greater than 1 ml (See column 5, lines 41-44). With respect to the recited thermal conductivity of the reaction portion, the reference of Gerarde discloses that the reaction portion (14) is made of glass (See column 4, lines 4-6) which is a material disclosed by the instant specification as a material with the claimed thermal conductivity (See page 53 of the instant specification). The reference of Gerarde discloses that the end of the reaction portion (14) can be sealed (See column 4, lines 48-54, and Figure 3).

With respect to claim 1, while the reference of Gerarde discloses the volume of liquid that the reaction portion (14) is intended to container, the reference fails to disclose the dimensions of the capillary tube, especially the thickness of the wall as recited in Claim 1.

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The reference of Gerarde ('494) discloses a pipette device similar to that of the reference of Gerarde ('804) (See Figure 1 of Gerarde ('804) and Figure 4 of Gerarde ('494)). The reference of Gerarde ('494) discloses that it is known in the art to employ capillary tubes with a wall thickness of about 0.1mm (See column 2, lines 58-68). The reference of Gerarde ('494) stresses that capillary tubes should not have an outer diameter exceeding 1mm (See column 3, lines 36-45) so as to protect against breaking when dropped.

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to manufacture the device of the primary reference using a known capillary tube as suggested by the reference of Gerarde ('494) for the known and expected result of providing a capillary tube that provides the volume required of the primary reference while constructed of dimensions that protect against breakage.

With respect to claim 2, the receiver portion (12) of Gerarde ('804) is made of a plastic material (See column 3, lines 1-10).

With respect to claim 3, the receiver portion (12) of Gerarde ('804) is funnel-shaped (See Figure 1).

With respect to claim 4, the reference of Gerarde ('804) discloses the use of plug (24) for sealing receiving portion (12).

With respect to claim 5, the tube suggested by the reference of Gerarde ('494) has an inner diameter of about 0.8mm and an outer diameter of about 1.0mm. While the reference of Gerarde ('804) discloses a volume of 20microliters, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to



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optimize the volume of the tube based merely on the desired volume of liquid to be drawn into the capillary vessel.

With respect to claim 6, the glass capillary is transparent (See column 4, line 4, of Gerarde ('804).

With respect to claim 19, while the reference of Gerarde ('804) discloses a volume of 20microliters, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to optimize the dimensions of the tube based merely on the desired volume of liquid to be drawn into the capillary vessel.

11. Claims 7, 9-12, 15-18 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerarde (US 3,518,804) in view of Gerarde (US 3,045,494) taken further in view of Hawes (US 3,556,659).

The combination of the references of Gerarde ('804) and Gerarde ('494) has been discussed above.

Claims 7, 12 and 20-22 differ by reciting that the closed end of the reaction portion of the device is formed to optimize optical transmissibility for light, especially light having a wavelength of about 400nm to about 800nm.

While the reference of Gerarde ('804) discloses that the end of the tube may be sealed by flame heating or by using wax (See column 4, lines 48-51), it is not clear if the sealed end is optimized for optical transmissibility for light, especially light having a wavelength of about 400nm to about 800nm.

The reference of Hawes discloses that it is conventional in the art to seal the end of a capillary tube using a cap (9) in the form of a glass plate (See column 5, lines 23-26).

In view of this teaching, it would have been obvious to one having ordinary skill in the art at the time the invention was made to seal the end of the capillary using a cap (9) as suggested by the reference of Hawes for the known and expected result of providing an alternative means recognized in the art to seal the end of a capillary tube. The method disclosed by the reference of Hawes provides a capillary tube that is capable of being optically interrogated through the end of the capillary tube. Additionally, since a glass plate is employed, it would be capable of passing light in the range of 400nm to 800nm as required of the instant claims.

With respect to the ratios of claims 7 and 15, the capillary tube suggested by the combination of the references of Gerarde ('804) and Gerarde ('494) would inherently have a volume-to-surface area ratio as recited in the claims.

With respect to claim 9, the reference of Gerarde ('804) discloses a volume of 20microliters.

With respect to claim 10, the tube suggested by the reference of Gerarde ('494) has an inner diameter of about 0.8mm and an outer diameter of about 1.0mm.

With respect to claim 11, the specifics of the interface between the funnel-shaped upper portion (12) and the lower portion (14) would have been well within the purview of one having ordinary skill in the art while maintaining a fluid seal between the separate elements (See column 3, lines 47-55).

With respect to claim 12, the use of a sealing plate as suggested by the reference of Hawes would result in a flat tip.

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With respect to claim 16, the lower portion (14) is made of glass and thus would be optically transmissible for light having a wavelength of about 400nm to 800nm.

With respect to claims 17 and 18, the reference of Gerarde ('804) discloses the use of plug (24) for sealing receiving portion (12).

With respect to claim 22, the thickness of the wall has been addressed with respect to the combination of the references of Gerarde ('804) and Gerarde ('494) when addressing claim 1.

### ***Response to Arguments***

12. Applicant's arguments filed 5/31/05 have been fully considered but they are not persuasive.

13. With respect to claim 1, Applicants argue that the rejection of claim 1 over the reference of von Behrens (See pages 6-7 of the response filed 5/31/05) has been overcome by including the wall thickness of the reaction portion of the device.

In response, the rejection of the claim under 35 USC 102 over the reference of von Behrens has been withdrawn. Note a new ground of rejection has been made over the combination of the references of Gerarde ('804) and Gerarde ('494).

14. With respect to claim 7, Applicants argue that the rejection of claim 7 over the reference of von Behrens (See page 7 of the response filed 5/31/05) under 35 USC 102 is improper and has been overcome by reciting that the closed end is formed to optimize optical efficiency.

In response, the Examiner is not persuaded because as shown in Figure 6, the end of the tube is sealed and made of the same material as that of the rest of the tube (glass) and therefore is made of a material that is optimized for optical transmissibility for light having a wavelength of from about 400nm to about 800nm. It is not clear how the sealed end of von Behrens is not capable of transmitting light in the claimed wavelength.

15. With respect to the rejection of claims 1-4, 6-9 and 16-18 over the reference of Gerarde ('804) under 35 USC 102, Applicants argue (See pages 7-8 of the response filed 5/31/05) that the rejection is improper for the following reasons:

- i) The device of Gerarde is used in a different manner than that of the instant invention.
- ii) The reference of Gerarde does not disclose a wall thickness of 0.1mm.

In response to comment i) above, while the intended use of the device of Gerarde is different from that of the instant invention, the device is structurally the same as the device recited in the instant claims and would be capable of being used in the manner intended by applicants.

In response to comment ii) above, this newly recited claim limitation has been addressed in a new ground of rejection in view of the combination of the references of Gerarde ('804) and Gerarde ('494).

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16. With respect to the rejection of claim 10 over the reference of von Behrens, Applicants argue (See pages 8-9 of the response filed 5/31/05) that the claimed dimensions would not be obviated by the disclosure of von Behrens.

In response, Applicants' comments have been found to be persuasive and the rejection of claim 10 over the reference of von Behrens under 35 USC 103 has been withdrawn. Note a new ground of rejection has been made over the combination of the references of Gerarde ('804), Gerarde ('494) and Hawes.

17. With respect to the rejection of claim 4 over the combination of the references of von Behrens and Gerarde, Applicants argue (See pages 9-10 of the response dated 5/31/05) that the combination of the references fails to address the wall thickness now claimed in claim 1.

In response, the rejection of this claim over the combination of the references of von Behrens and Gerarde has been withdrawn. Note a new ground of rejection has been made over the combination of the references of Gerarde ('804) and Gerarde ('494).

18. With respect to the rejection of claims 17 and 18 over the combination of the references of von Behrens and Gerarde, Applicants argue (See page 10 of the response dated 5/31/05) that the combination of the references fails to address optimized optical transmissibility of claim 7.

In response, the Examiner is of the position that the reference of von Behrens meets the claim limitation of claim 7 for reasons discussed previously.

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19. With respect to the rejection of claim 12 over the combination of the references of von Behrens and Hawes, Applicants argue (See pages 10-13 of the response filed 5/31/05) that Hawes cannot be properly combined with the reference of von Behrens.

In response, the rejection of claim 12 over the combination of the reference of von Behrens and Hawes has been withdrawn in favor of a new ground of rejection involving the combination of the references of Gerarde ('804), Gerarde ('494) and Hawes.

### ***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB